

## Transforming Care for Critical Women's Health Needs

## **Opportunity Overview**

Non-Confidential

Arstat Pharmaceuticals, Inc.





#### **Arstat Pharmaceuticals - Executive Summary**

#### For the first time, addressing high women's health priorities:

Safe and effective hormonal contraception for 20 million US women with high BMI (overweight and obese)

Significant decline in harmful surgeries for uterine fibroids and endometriosis (>13 million hysterectomies in the US)

- A world-class, advanced four-product pipeline for >60 million US women
- Two Phase III-ready assets (confirmed by the FDA); two likely blockbusters
- 16 US and EU patents from a co-inventor of the best-selling US oral contraceptive
- Raising a pre-IPO bridging round: \$1M for 8% of the public company
- Profitable exit options for investors







## One of the best pipelines in women's health

First-to-market, transformational products for critical unmet needs



• Strong supporting data; a low-risk, rapid 505(b)(2) NDA pathway



The first and only oral contraceptive designed for women with high BMI (>50% of the market); projected sales - \$1-2B/year.



First-in-category medicated vaginal ring for uterine fibroids and endometriosis. Optimal use of the best class of drugs; >\$1B/year.



**First-in-category single non-hormonal therapy** for painful, heavy menstrual periods. **Potential first-line for a prevalent disorder.** 



The first oral contraceptive for women with cardiovascular risk factors. The safest option for normal-weight pill users.

<sup>\*</sup> The clinical development stage after the completion of pre-clinical activities



### Summary of Markets and Projected Sales

- Across the entire portfolio:
  - an addressable market: > 60 million US women (> 800 million worldwide)
  - projected peak annual gross sales (US): at least \$2.9B, could be close to 4.8B
- NUVOCEPT & PREMRING are potential leaders in multi-billion-dollar markets

Product	Addressable US Market	Peak Gross Annual Sales (US Only)*		
		"Base" Scenario	"Upside" Scenario	
NUVOCEPT	≈ 20 million	\$1,070M	\$2.260M	
DUACEPT	≈ 3 million	\$140M	\$180M	
PREMRING - Uterine Fibroids	≈ 9 million	\$570M	\$800M	
PREMRING - Endometriosis	≈ 5 million	\$760M	\$890M	
ENHANTA (Rx)	>25 million	\$430M	\$650M	
Total	≈ 62 million	\$2,970M	\$4,780M	



\*All assessments utilize very conservative market share and pricing assumptions



## **Arstat Pharmaceuticals: Leadership**

#### Arkady Rubin, PhD, Founder, Inventor, President/CSO



- ➤ Industry veteran (J&J, Pfizer) who designed and executed numerous clinical studies and contributed to the development and FDA approval of top women's health products
- ➤ Co-inventor\* of Ortho Tri-Cyclen Lo®, one of the best US oral contraceptives (\$1.8B/year in current market conditions). Authored 20+ patents and multiple publications

#### Jon Stelzmiller, Acting CEO, Prospective Board Member



- A proven business leader with 4 decades of achievements in specialty markets, including women's health. A builder of high-performing teams and innovative market solutions.
- Career highlights: President of US Specialty Business (Lupin); Senior VP & General Manager of a \$1B Women's Healthcare Franchise (Bayer); Vice President (Pfizer)

#### Andrea S. Lukes, MD, MHSc, FACOG, Chief Medical Officer



- For 8 years, served as a Chief Medical Officer at Health Decisions, a leading women's health CRO (sold to Premier Research); Owner of a private practice/research center
- A well-published principal investigator in over 150 clinical trials; Consultant to major women's health companies (e.g. Myovant, Bayer, Abbvie), presenter at FDA meetings.



### **Advisory Board**

120+ years of developing leading women's health brands













## Elite Group of Women's Health Leaders and Advocates (Past and Current Advisors)

Elizabeth Garner, MD, MPH A Past President of the American Medical Women's Association	Barbara Levy, MD, FACOG. FACS A health care access expert, a previous ACOG's VP for health policy	Jeffrey M. Cohen Founder & CEO of 3 life sciences companies with successful exits.
Karen Drexler, BSE, MBA A former CEO, recipient of the Female Entrepreneur of the Year Award		Russell Barrans, MBA A commercial expert who introduced widely known contraceptive brands.
Agis Kydonieus, PhD A founder of the Controlled Release Society, 10 books on drug delivery	<u> </u>	Marina Ness, MPH Public health professional in patient- centric market research

We are seeking senior executives, advisors, and Company's Board members



# For the First Time, Addressing a Major Public Health Priority Safe and Effective Hormonal Contraception for Women with High BMI



≈ 40% of US women have obesity\*



≈ 25% women are overweight\*

#### 20 million US women with high BMI need reliable birth control

— with common choices (hormonal pills, patches, and rings) performing poorly in this population



Obese women have up to 4.3x greater chance of an unintended pregnancy\*\*



Obese women have up to 3.7x greater odds of terminating a pregnancy\*\*

The overruling of Roe disproportionally impacts women with high BMI, making their need for dependable contraception more urgent than ever.

<sup>\*</sup> The rates are for reproductive-age US women. Body Mass Index (BMI) categories: - Obese - BMI ≥ 30 kg/m²; Overweight - BMI 25 - 29.9 kg/m².

<sup>\*\*</sup> Doskoch P. Obesity linked to elevated risk of unintended pregnancy, abortion, STDs. Perspectives on Sexual and Reproductive Health. 2010;42:276.



## **NUVOCEPT**<sup>TM</sup> - A Truly Powerful Asset

# The first and only oral contraceptive explicitly designed for women with high BMI

- 1 Unprecedented Label
  New indication and unique claims
  for a lasting competitive advantage
- 2 Phase III-Ready
  Successful meeting¹ with the FDA;
  an abbreviated program is finalized
- 3 Projected Sales \$1-2B/year

It will likely dominate a multi-billion-dollar segment of the US market

- 4 Rapid, Low-Cost R&D
  < \$20M in total costs and <3.5
  years to the FDA approval
- 5 Low-Risk

  Validated by the FDA acceptance of safety and efficacy projections
- 6 Strong IP Portfolio
  Eight US patents and an EU patent covering major European markets

The FDA approved the first-ever contraceptive clinical program dedicated to overweight and obese women.

**NUVOCEPT**<sup>TM</sup>

<sup>&</sup>lt;sup>1</sup>While the meeting was formally classified as a pre-IND meeting, it accomplished all objectives of a pre-Phase III meeting



# <u>Problem</u>: Marketed Contraceptives are Not Intended for or are Contraindicated in Women with High BMI

## Excluding from pivotal trials

Most Phase III trials excluded women with high BMI, and many approved contraceptives are marketed to an unstudied population

## Delivering suboptimal doses

Due to poor drug absorption, women with high BMI receive 70-80% of the nominal dose<sup>1,2,3,4,5</sup>, with unsatisfactory pregnancy prevention

## Increasing cardiovascular risks

Modern contraceptive formulations are not suitable to women with high BMI due to a higher rate of serious cardiovascular events<sup>6,7,8</sup>



#### **Unacceptable performance of All Recently Approved Combined Hormonal Contraceptives:**

- Generess®(2011): Risk of pregnancy increases by 72% for women with obesity<sup>9</sup>
- Quartette®(2013): Pregnancy rates greater by 86% for women with obesity<sup>10</sup>
- Annovera®(2018): Due to safety risks, clinical testing of women with obesity was terminated¹¹
- Twirla®(2020): Contraindicated in women with obesity; a limitation of use in overweight women<sup>12</sup>
- Nextstellis®(2022): Due to decreasing effectiveness, limitation of use in women with obesity<sup>13</sup>

Selected Sources: <sup>1</sup>Edelman (2009), <sup>2</sup>Edelman (2014), <sup>3</sup>Westhoff (2010), <sup>4</sup>Evra (2001), <sup>5</sup>Robinson (2013), <sup>6</sup>Arstat Pharmaceuticals, Inc. (Data on file), <sup>7</sup>Abdollahi (2003), <sup>8</sup>FDA (2011), <sup>9</sup>Yamazaki (2015), <sup>10</sup>NDA 204061 (2013), <sup>11</sup>Annovera (2018), <sup>12</sup>Twirla (2020), <sup>13</sup>Nextstellis (2021)



## Our Solution: FDA-Endorsed NUVOCEPT<sup>TM</sup>

Novel oral contraceptive uniquely formulated for women with high BMI

Highly **Effective** 

Up to 3 times lower pregnancy rates vs. leading brands

Very Safe

2 – 3-fold reduced risk of serious side effects vs. modern pills

The FDA has recognized the importance of NUVOCEPT and allowed its move to Phase III

- ✓ NUVOCEPT efficacy and safety projections accepted
  - no need for Phase I or Phase II data\*
  - the FDA has agreed with the immediate dosing of 1,500+ women

#### "Women will LOVE it"

(Andrea S. Lukes, MD, MHSc FACOG)

Dr. Lukes conducted >80 trials of women's health products.

- ✓ NUVOCEPT's unprecedented label is conceptually endorsed
  - **Beneficial claims** for overweight and obese women
  - No contraindications or limitations of use
- ✓ The first-ever program entirely dedicated to women with high BMI is finalized

<sup>\*</sup>At least seven other approved oral contraceptives also started clinical testing in Phase III



## NUVOCEPT™: Ready for a Phase III US Study

**Multiple Precedents:** Recently approved products with a **direct move to Phase III**:

Oral Contraceptive	NDA Number/ Approval Year	·	
Seasonale®	21-544/2003	LNG/EE*	YES
Seasonique®	21-840/2006	LNG/EE*	YES
Lybrel®	21-864/2007	LNG/EE*	YES
Loseasonique®	22-262/2008	LNG/EE*	YES
Loestrin® 24 Fe	21-871/2006	NETA**/EE	YES
Lo Loestrin® Fe	22-501/2010	NETA**/EE	YES
Generess® Fe	22-573/2010	NETA**/EE	YES

Unprecedented: A direct move to Phase III in a vulnerable, poorly served population

<sup>\*</sup>Same progestin/estrogen combination as in Nuvocept;

<sup>\*\*</sup> Norethindrone acetate



## NUVOCEPT - Projected Peak Sales: \$1-2B/year (US Only)

Valuation Scenarios	Market Share*	Rebates	Gross Sales	Net Sales
"Base"	10%	50%	\$1,070M	\$963M
"Upside"	15%	30%	\$2,260M	\$2,034M



\*With exclusive label and superior safety and efficacy, **NUVOCEPT will likely be accepted as**the 1<sup>st</sup> line oral contraceptive for women with high BMI (≈ 60% of the market)

Conservative Marketing Assumptions

Sales Forecasting Metrics	"Base"	"Upside"
Market Size, Monthly TRx (m)	100	100
Market Share at Peak	10%	15%
Filled Prescriptions at Peak (m)	10	15
Gross (AWP**) Price (\$)	215	215
Gross Revenue (m)	2,150	3,225
Rebates and discounts	50%	30%
Net selling price per monthly Rx (\$)	107	150
Net Revenue (m)	1,070	2,260
COGS Ratio	10%	10%
Gross Profit (m)	963	2,034

<sup>\*\*</sup>AWP = Average Wholesale Price; from Information for Vermont Prescribers of Prescription Drugs: https://www.compliance.bayerweb.com/AWP/Bayer\_2025M01\_VermontShortForm\_NATAZIA.pdf\_



## Why PREMRING<sup>™</sup> for Uterine Fibroids and Endometriosis?

#### To fight severe reproductive disorders that destroy millions of lives

- 25%\* of US women (>20 million) have symptomatic uterine fibroids
- 10%\* of US women (>10 million) suffer from endometriosis
- Terrible menstrual cramps, pelvic pain, heavy menstrual bleeding, infertility
- 400,000 hysterectomies/year; at least 13 million US women had their uterus removed because of uterine fibroids and endometriosis

## Unlike other treatments, designed as an alternative to harmful surgeries

- Low doses of a well-studied SPRM\*\* are delivered by a novel route directly to affected tissues
- Unrivaled efficacy and safety permit comfortable long-term treatment (not an option for other hormonal medications), drastically reducing the need for hysterectomies

## A breakthrough solution for highly prevalent and undertreated conditions.

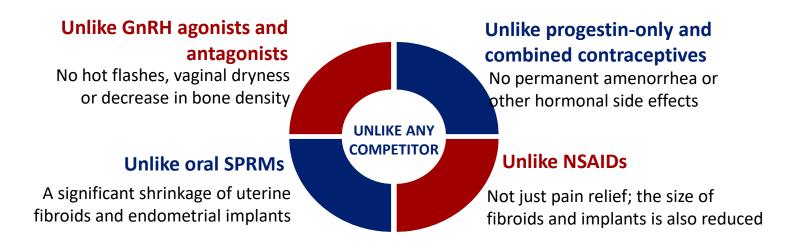
<sup>\*</sup> Prevalence among women aged 15-49 years

<sup>\*\*</sup> Selective Progesterone Receptor Modulator



## PREMRING<sup>TM</sup> - Differentiation and Market Opportunity

Expected US gross sales - \$1.33B/year; >\$1B in each indication (worldwide)



Competitors focus on the symptoms.

PREMRING is designed as a curative option.

Compelling supporting data greatly reduces the R&D risks and ensures a high probability of PREMRING approval



## **Arstat Pipeline: Additional Details**

**Other Products: Highlights** 



#### **ENHANTA**<sup>TM</sup>

- Novel non-hormonal therapy for painful, heavy menstrual periods (>25 million US women)
- Proprietary drug combination (Rx and OTC), with Phase III-ready: \$5M in total costs if developed in no competition.
- Phase IIb asset; could be ready for Phase III (FDA confirmation needed)
- Projected US Gross Sales (Rx) -\$430M



#### **DUACEPT<sup>TM</sup>**

- Novel oral contraceptive for 3 million normalweight women with cardiovascular risk factors.
- parallel with NUVOCEPT.
- In some countries, it may be approved with no new clinical data.
- Projected US Gross Sales -\$140M

#### Large and growing IP portfolio (16 granted US and EU patents)

**15 US Patents:** 9,675,622; 9,925,199; 10,111,887; 10,463,678; 10,537,582; 11,103,515; 11,717,527; 10,251,836; 11,116,718; 10,532,037; 10,709,679; 11,351,132; 11,833,126; 12,005,138; 12,390,476. **10+ more US patents planned**;

European (EU) Patent: EP 2790688 B1.

Issued and new US patents and regulatory exclusivity are expected to protect the products until at least 2037, possibly much longer

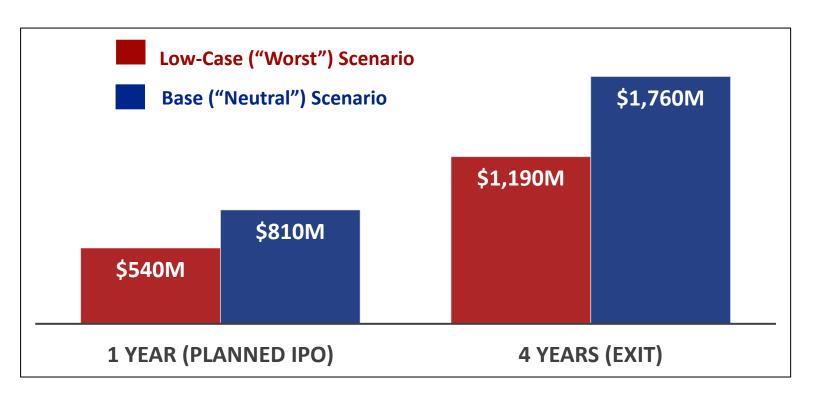
The Sole Inventor and Owner, Founder - Arkady Rubin, PhD





### **Company Valuation\***

#### The company's portfolio value (NPV\*\*) at key milestones



<sup>\*</sup> In collaboration with **Bio-strategy Analytics**, Arstat determined the portfolio value at 1 year and 4 years (after the approval of NUVOCEPT/DUACEPT and the completion of PREMRING and ENHANTA R&D). A 47-page report is prepared per the best industry standards.

<sup>\*\*</sup>The NPV (Net Present Value) is calculated using the Discounted Cash Flow (DCF) and Risk-Adjusted (eNPV) methods.



### **Exit Opportunities and ROI Targets**



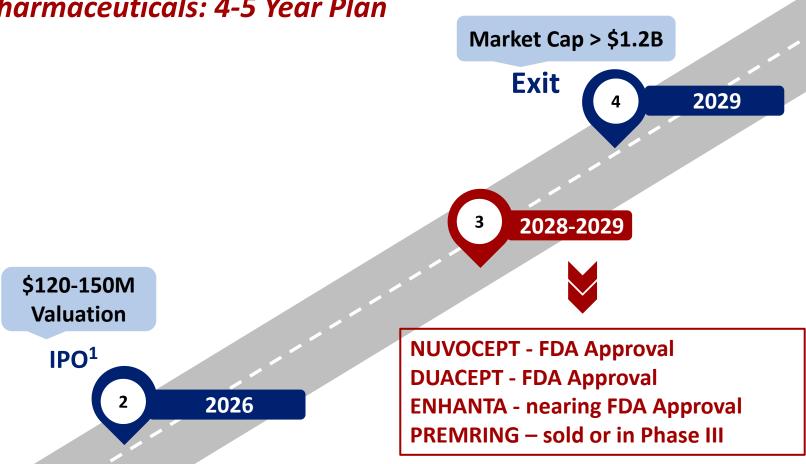


<sup>\*</sup>Conservative estimate: assuming the IPO valuation is <30% of the low-case portfolio value. See slide 16.

<sup>\*\*</sup>Conservative estimate: assuming the low-case valuation scenario at the exit. See slide 16.



#### Arstat Pharmaceuticals: 4-5 Year Plan



\$10M Valuation 2025 **Bridge Financing (\$1M)** 

<sup>&</sup>lt;sup>1</sup>Subject to market conditions; otherwise, a reverse merger or Series B rou<u>nd</u>



## A Likely IPO (around Q2 of 2026): Strategic Considerations

- Investment bankers consider Arstat a potentially great public company
   rapid, low-risk, low-cost R&D, huge markets, clear and achievable strategic goals
- Validated by two engagement offers for valuable IPOs
- Impeccable market timing for NUVOCEPT due to the overruling of Roe v. Wade
- More advanced pipeline than 2/3 of biopharma IPOs\*

#### A notable precedent: Myovant Sciences

- Women's health pharma company had the largest biotech IPO of 2016, eight months after its launch, with a few employees\*\*
- With a pipeline arguably comparable to Arstat's
- From the initial funding round (\$7M) to a \$2.9B exit in ≈ 6 years



<sup>\* &</sup>lt;u>www.mtspartners.com/wp-content/uploads/sites/2/2016/08/Early-Stage-IPOs-2012-2018-August-2018.pdf</u>

<sup>\*\* &</sup>lt;a href="https://medcitynews.com/2016/10/myovant-sciences-rallies-218-million-biotech-ipo/">https://medcitynews.com/2016/10/myovant-sciences-rallies-218-million-biotech-ipo/</a>



### IPO Comparables – Arstat targets are very conservative

#### Valuable recent IPOs with a lead asset in Phase III (no revenues)\*

Company	Symbol	IPO Date	Money Raised	Market Cap	Percent Equity	Stage
Alumis, Inc.	ALMS	6/28/2024	\$300M	\$958M	31%	Phase III
Fractyl Health, Inc.	GUTS	2/2/2024	\$110M	\$714M	15%	Phase III
ArriVent BioPharma, Inc.	AVBP	1/26/2024	\$175M	\$575M	30%	Phase III
CG Oncology Inc.	CGON	1/25/2024	\$380M	\$1.206M	32%	Phase III
Adlai Nortye Ltd.	ANL	9/29/2023	\$50M	\$720M	8%	Phase III
Neumora Therapeutics, Inc.	NMRA	9/15/2023	\$250M	\$2.585M	10%	Phase III
RayzeBio, Inc.	RYZB	9/15/2023	\$311M	\$940M	33%	Phase III

#### Arstat's IPO targets (\$30-50M raised; \$120-150M market cap) are very conservative

— 20-25% of median values calculated from the above table

#### A possible fast-track IPO

— if market conditions are not favorable, the company may consider a fast-track IPO initially focusing on the lead asset (NUVOCEPT) and, optionally, DUACEPT



# Critical R&D Milestones and Capital Requirements Highlights:

- NUVOCEPT/DUACEPT Phase III study will start immediately after the IPO and be completed in 1.5 years with well-established approvability
- Major R&D milestones for other products will be achieved in 2-2.5 years, significantly increasing the company's market cap and the mid-term return for investors
- Total R&D costs for planned clinical programs are ≈ \$35M

Products	Critical Post-IPO timelines	Total R&D Costs
NUVOCEPT	<ul> <li>≈ 1.5 years to the completion of Phase III</li> <li>≈ 2 years to the NDA submission;</li> <li>≈ 3 years to the FDA approval</li> </ul>	\$19.6M (including \$16M* for Phase III study)
DUACEPT	Same timelines as for NUVOCEPT (both products developed in parallel)	\$4.6M
PREMRING	<ul><li>≈ 1 year to the IND</li><li>≈ 2.5 years to the completion of Phase IIb</li></ul>	\$6.3M
ENHANTA	<ul><li>≈ 0.5 years to the IND</li><li>≈ 2 years to the completion of Phase IIb</li></ul>	\$4.8M

<sup>\*</sup> Verified by detailed cost estimates from 3 CROs



#### Arstat Pharmaceuticals: The Ask and Action Plan

Arstat is raising \$1M (Bridge Financing) ahead of a planned IPO

\$10M Valuation Cap (Post-Money)

The investors of this round are expected to own 8% of the public company

#### **Major Tasks and Next Steps**

- Finalize the senior executive team and assemble a well-connected board of directors
- Prepare the IND for NUVOCEPT/DUACEPT, identify the CRO for a Phase III study
- Arrange two more meetings with the FDA (ENHANTA and PREMRING)
- Conduct IPO-readiness activities and expand outreach to potential strategic partners
- An IPO Underwriting Agreement (Q4 of 2025)
- \$30-50M IPO at a targeted IPO valuation of \$120-150M (around Q2 of 2026)

An optional expansion of this round (up to \$2M) will support additional R&D, PR, and IR activities, further increasing the IPO valuation



#### **IPO Time and Cost Estimates**

16 - 22 weeks (≈ 4 - 5 months) to the IPO

 $\square \approx $500.000$  in pre-IPO expenses

Preparation, Registration (4-6 weeks)

SEC Review, Listing Approval (8-12 weeks)

Roadshow (3 weeks)

Closing (1 week)

1

2

Expenses	Pre-Closing	At Closing	Total
Legal	\$225,000	\$225,000	\$450,000
Accounting and audit fees	\$75,000	\$75,000	\$150,000
Printing	\$30,000	\$20,000	\$50,000
SEC fees, other regulatory costs	\$30,000	\$45,000	\$75,000
Roadshow	\$50,000	\$0	\$50,000
Advances to Underwriter*	\$50,000	\$0	\$50,000
Miscellaneous	\$30,000	\$0	\$30,000
TOTAL	\$490,000	\$365,000	\$855,000**

<sup>\*</sup> Due diligence, background checks, etc.

<sup>\*\*</sup> Underwriter's'fees paid at closing are not included



### Summary of the Investment and Partnership Opportunity

- For the first time, addressing huge public health priorities
  - Reliable contraception for women with high BMI
  - Significant decline in harmful surgeries for uterine fibroids and endometriosis
- A 4-product pipeline includes two Phase III assets and two likely blockbusters
- 16 patents from a co-inventor of the best-selling US oral contraceptive
- **Seeking senior executives and Board members**
- Raising a pre-IPO bridging round: \$1M for 8% of the public company
- An exceptional near-term exit option (a likely IPO in  $\approx$  1 year)



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